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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,366	01/23/2006	Rolf Hartung	7601/8-4486	5556

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LAW OFFICE OF MICHAEL A. SANZO, LLC
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ROCKVILLE, MD 20855

EXAMINER

YOUNG, SHAWQUTA

ART UNIT	PAPER NUMBER
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1626

MAIL DATE	DELIVERY MODE
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05/10/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/565,366

Applicant(s)

HARTUNG ET AL.

Examiner

Shawquia Young

Art Unit

1626

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-33 and 35-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 28-33 and 35-40 is/are allowed.
- 6) ☒ Claim(s) 41-43 is/are rejected.
- 7) ☒ Claim(s) 44-47 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-945)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 28-33 and 35-47 are currently pending in the instant application.

Applicants have cancelled claim 34 in an amendment filed on February 23, 2011.

Claims 41-43 are rejected, claims 44-47 are objected and claims 28-33 and 35-40 are considered allowable in this Office Action.

I. *Response to Arguments/remarks*

Applicants' amendment, filed on February 23, 2011, has overcome the rejection of claims 28, 32, 33, 35-40 and 44-47 under 35 USC 103(a) as being unpatentable over Minnaard, et al. (Synthetic communications, 29, 1999) in view of Schuda, et al. (J. Org. Chem. 1988, 53) and the objection of claims 29-31 as being dependent upon a rejected based claim. The above rejection and objection have been withdrawn.

However, Applicants have not overcome the rejection of claims 41-43 under 103 as being unpatentable over Minnaard, et al. in view of Schuda, et al. Applicants argue that by comparing the results in the specification with the results in the prior art references, it should be apparent that Applicants report yields comparable to those of the cited references in less than half of the time reported by Schuda and in less than one fourth the time reported by Minnaard. However, the Examiner wants to point out that these comparative results are not present in the specification or in the form of a declaration and therefore are only considered mere arguments. The Examiner maintains the position as stated in the previous Office Action, that merely modifying the process conditions which includes concentration, temperature, reaction times, etc. is not

a patentable modification absent a showing of criticality (See *In re Aller*, 220 F. 2d 454, 105 USPQ 233 (CCPA 1955)). Therefore in the absence of substantial evidence showing unexpected results, Applicants' arguments have failed to overcome the pending 103 rejection. The Examiner has maintained the rejection of claims 41-43 under 35 USC 103 as being unpatentable over Minnaard, et al. in view of Schuda, et al.

II. ***Rejection(s)***

35 USC § 103 - OBVIOUSNESS REJECTION

The following is a quotation of 35 U.S.C. § 103(a) that forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Graham v. John Deere Co. set forth the factual inquiries necessary to determine obviousness under 35 U.S.C. § 103(a). See *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Specifically, the analysis must employ the following factual inquiries:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 41-43 are rejected under 35 U.S.C. § 103(a) as being unpatentable over

Minnaard, et al. (Synthetic communications, 29, 1999) in view of *Schuda, et al.* (J. Org. Chem. 1988, 53). Applicants claim a process for the hydrogenation of a compound selected from the group consisting of : L-phenylalanine, D-phenylalanine, L-phenylglycine, D-phenylglycine, L-tyrosine or D-tyrosine, comprising hydrogenating said compound in the presence of a platinum-rhodium mixed catalyst wherein said process produces a yield of greater than 94% after a reaction time of about 6 to 8 hours.

The Scope and Content of the Prior Art (MPEP §2141.01)

Minnaard, et al. teaches the synthesis of enantiomerically pure cyclohexylglycine by hydrogenating phenylglycine using a rhodium catalyst and rhodium catalyst on support. The reaction resulted in a high yield and no racemization occurred. The prior art reference also teaches the use of palladium, platinum or ruthenium as catalysts in the synthesis.

Schuda, et al. teaches the hydrogenation of L-phenylalanine by using a platinum catalyst (i.e. PtO₂) and the reaction result in a high yield and does not undergo racemization.

The Difference Between the Prior Art and the Claims (MPEP §2141.02)

The difference between the prior art of *Minnard, et al.* in view of *Schuda, et al.* and the instant invention is that the instant invention uses a mixed platinum-rhodium catalyst whereas the prior art teaches the use of platinum and rhodium separately.

Prima Facie Obviousness-The Rational and Motivation (MPEP §2142-2413)

Applicants are claiming a process for the hydrogenation of a compound selected from the group consisting of : L-phenylalanine, D-phenylalanine, L-phenylglycine, D-phenylglycine, L-tyrosine or D-tyrosine, comprising hydrogenating said compound in the presence of a platinum-rhodium mixed catalyst. The prior art teaches a similar process wherein either a platinum catalyst or a rhodium catalyst is used and both catalyst are successful in the hydrogenation reaction.

In In re Crockett, et al., 126 USPQ 186, it was well established that when the prior art teaches the use of two catalysts, the idea of combining them would flow logically from prior art and claim to joint use is not patentable. Also, it was well established the selection of reaction conditions (i.e., temperature, concentration, reaction times, etc.) is more optimization by mere modification of routine experimentation and within one skilled in the art. So Applicants modifying the reaction time to about 6 to 8 hours vs. for example, 18 hours as seen in the prior art, is considered mere modification of routine experimentation and within one skilled in the art. For example, it is obvious to combine rhodium and platinum catalysts in a hydrogenation process of aryl substituted amino acids when the art teaches the use of each catalyst separately in the same type of reaction with reasonable expectation of success. Therefore, it would have been prima facie obvious to one having ordinary skill in the art at the time the invention was made to use a mixed platinum-rhodium catalyst in the hydrogenation of a compound according to claim 41 based on the teachings in the prior art. A strong prima facie obviousness

has been established. Applicants are suggested to provide a showing of unexpected results in the form of a declaration to overcome the 103 rejection.

III. Objection

Dependent Claim Objections

Dependent Claims 44-47 are objected to as being dependent upon a rejected based claim. To overcome this objection, Applicant should rewrite said claims in an independent form and include the limitations of the base claim and any intervening claim.

IV. Conclusion

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawquia Young whose telephone number is 571-272-9043. The examiner can normally be reached on 7:00 AM-3:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shawquia Young/

Primary Examiner, Art Unit 1626